

PATENT  
09/718,308  
Docket: 093/002

### REMARKS

This paper is responsive to the Office action dated December 5, 2001 (Paper No. 4), which is the first Action on the merits of the application.

Claims 29-33 are pending in the application and under examination, and stand variously rejected. Upon entry of this Amendment, claims 30-36 are pending and under examination.

Applicants' representative wishes to express his gratitude to examiners Thaian Ton and Deborah Clark for meeting with him for a very productive interview on January 9, 2002. Suggestions made by the Examiners are incorporated into this Amendment.

Reconsideration and allowance of the application is respectfully requested.

#### Amendments to the claims

Upon entry of this Amendment, claim 29 has been canceled, and will be presented in another application. This is done to facilitate prosecution of the application, and is not intended as a dedication to the public of any subject matter disclosed in the specification or previously claimed.

Claim 30 has been amended in a manner which does not further limit the scope of the claim. Accordingly, coverage is maintained for all equivalents of the subject matter in this claim for which applicants were previously entitled.

The amendment to claim 30 is supported by the claim as previously presented. New claim 34 is supported in the specification *inter alia* in Example 1 (page 50 ff.). New claims 35-36 are supported *inter alia* on page 24, lines 19-28.

#### Rejection under 35 USC § 102:

Claims 29-32 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,030,105, as evidenced by EP 0953 633 A1; Hayashi et al. (Mol. Pathol. 52:19, 1999); and Alberts et al. ("Molecular Biology of the Cell", pp. 66 & 85, 1989). Claim 30 further stands rejected as being anticipated by Thomson et al. (Science 282:1145, 1998).

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The Office Action indicates that referring to the cell population as progeny of an established hES cell line is a product-by-process description, and the Office cannot distinguish the cells from other cells having the same characteristics.

The rejection of claim 30 is made by asserting that the first cell population is indistinguishable from the human embryonic stem cells in the Thomson reference, and the second cell population is indistinguishable from the hepatocytes cultured in EP 0953 633 A1, Hayashi et al., or Alberts et al.

Rejection of claim 30 was based on a combination of references, which cannot be made under 35 USC § 102. Furthermore, claim 30 cannot be rejected on this basis under 35 USC § 103(a), since the two cell populations in the claims have a special relationship not taught or suggested by the references. Specifically, since the second cell population having characteristics of hepatocytes is the progeny of the hES cell line of the first population, the two populations will have essentially the same genomic DNA (with the possible exception of any genetic modifications made to cells in either population by recombinant DNA technology). The Thomson reference teaches that an entire in vitro fertilized embryo is harvested in order to establish an embryonic stem cell line. Combining such cells with a population of hepatocytes taken from a mature liver, as taught by EP 0953 633 A1, Hayashi et al., or Alberts et al., would not produce a set of cells that share genomic DNA in the same fashion.

Claims 31-36 now all depend from claim 30, incorporating its limitations, and are also free of the art of record.

Applicants also respectfully disagree with the rejection of claim 29. This claim covers a cell population with hepatocyte characteristics that are progeny of an established hES cell line. Again, this requires that the claimed cell population has essentially the same genomic DNA (with possible genetic modifications) as the established hES cells. While the undifferentiated hES cells are not part of the product appearing in the claim, the relationship is nonetheless an important one that has possible implications for the use of the claimed cell line in therapy. The Office Action justifies the assertion that the claimed cells are indistinguishable from hepatocytes because the Office is not able to manufacture products (citing *In re Best*, 195 USPQ 430, 433 (CCPA 1977)). This justification relates to product-by-process claims, but is

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not applicable to the features recited in claim 29. The claim does not refer to the process by which the cells were obtained, but by its relationship to the parental hES cell line — which is readily ascertained.

Solely to expedite prosecution of this application, claim 29 has been canceled, and will be presented along with these arguments in a related application.

Withdrawal of this rejection is respectfully requested.

Rejection under 35 USC § 112:

Claims 29, 31, and 32 stand rejected under 35 USC § 112 ¶ 2 as indefinite for reciting different numbers of characteristics and different percentages. Claims 31 and 32 now depend from Claim 29, but the relationship has been maintained.

Applicants respectfully disagree with the rejection. Claim 31 requires that 60% of the cells in the second population have at least five of the characteristics, which satisfies the requirements of claim 30 (requiring that *at least* 60% of the cells have *at least* three of the characteristics, which is satisfied if 60% have five of the characteristics). Claim 32 requires that 80% of the cells in the second cell population have at least seven of the characteristics, which satisfies the requirements of claim 30 (requiring that *at least* 60% of the cells have *at least* three of the characteristics, which is satisfied if 80% have seven of the characteristics).

Withdrawal of this rejection is respectfully requested.

Rejection under 35 USC § 103:

Claims 29-33 stand rejected under 35 USC § 103 as being unpatentable over U.S. Patent No. 5,030,105 in combination with Bodnar et al. (Science 279:349, 1998).

Applicants respectfully disagree. Claim 30 is patentable over the 5,030,105 patent for reasons discussed earlier. Bodnar et al. describe the use of telomerase expression vectors, which is relevant only to claim 33. The Bodnar reference does not cure the deficiency in the 5,030,105 patent with respect to the relationship between the two cell populations.

Withdrawal of this rejection is respectfully requested.

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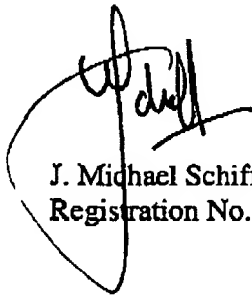
Conclusion

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn in light of the remarks made herein. These papers are believed to place the application in condition for allowance, and an early Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicants hereby request a further interview by telephone.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief. The Assistant Commissioner is hereby authorized to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139.

Respectfully submitted,



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